***NOT FOR PUBLICATION**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, et al., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. 07-4459 (FLW)
CELGENE CORPORATION, et al., Plaintiffs, v. ACTAVIS SOUTH ATLANTIC LLC and ABRIKA PHARMACEUTICALS, INC., Defendants.	Civil Action No. 07-5367 (FLW)
CELGENE CORPORATION, et al., Plaintiffs, v. INTELLIPHARMACEUTICS CORP., Defendant.	Civil Action No. 07-4854 (FLW)

CELGENE CORPORATION, et al., Plaintiffs, v. BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC., Defendants.	Civil Action No. 07-5552 (FLW) **OPINION**

WOLFSON, United States District Judge:

Presently before the Court are motions filed by Defendants Teva Pharmaceuticals USA, Inc. ("Teva"), Actavis South Atlantic LLC and Abrika Pharmaceuticals, Inc. ("Actavis"), IntelliPharmaCeutics Corp. ("IPC"), and Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. ("Barr") (collectively, "Defendants") in four separate actions for judgment on the pleadings to strike Plaintiffs', Celgene Corporation, Novartis Pharmaceuticals Corporation, and Novartis Pharma AG (collectively, "Plaintiffs"), claims of willful infringement pursuant to Fed. R. Civ. P. 12(c) because the mere filing of an Abbreviated New Drug Application ("ANDA") cannot constitute willful infringement.[1] Plaintiffs agree that the filing of an ANDA, alone, cannot

[1]In each of the four actions, Celgene Corp., et al. v. Teva Pharmaceuticals USA, Inc., Civil Action No. 07-4459, Celgene Corp., et al. v. Actavis South Atlantic LLC, et al., Civil Action No. 07-5367, Celgene Corp., et al., v. IntelliPharmaCeutics Corp., Civil Action No. 07-4854, Celgene Corp., et al. v. Barr Laboratories, Inc., et al., Civil Action No. 07-5552, defendants file a Motion for Judgment on the Pleadings pursuant to Rule 12(c). Specifically, Teva seeks to strike allegations of willful infringement, paragraphs 25, 30, 35, 40, and 45; Actavis seeks to strike allegations of willful infringement, paragraphs 28, 33, 38, 43, and 48; IPC seeks to strike allegations of willful infringement, paragraphs 26, 31, 36, 41, and 46, with prejudice; and Barr seeks to dismiss Plaintiffs' allegations of willful infringement, striking paragraphs 29, 35, 41, 47, and 53, with prejudice.

support a claim for willful infringement and thus, propose a stipulation in which they agree to strike these allegations without prejudice to their right to seek leave to renew the willfulness claim in the future if any further evidence of such is adduced. Teva and Actavis seek judgment on the pleadings striking the willful infringement allegations of the patents-in-suit and IPC and Barr seek orders dismissing Plaintiffs' willful infringement claims with prejudice. Plaintiffs filed suit under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2) ("the Act"), alleging that Defendants infringed on five of their patents. The Court has considered the parties' moving, opposition, and reply papers. As Defendants rely upon the Brief of Teva filed in support of its Motion for Judgment on the Pleadings and the motions are identical in substance, the Court decides these motions together herein. For the reasons that follow, the Court grants Defendants' Motions for Judgment on the Pleadings to strike the paragraphs in Plaintiffs' Complaints relating to willful infringement.[2]

I. Factual Background and Procedural History

A. The Hatch-Waxman Act

Plaintiffs filed suit under Drug Price and Patent Term Restoration Act of 1984, more commonly referred to as the Hatch-Waxman Act, 35 U.S.C. § 271 ("the Act"), which modified

[2]The parties' disagreement over whether the paragraphs at issue should be struck with prejudice serves as the basis for the instant motions. Similar to the decisions of the other courts in this District, the Court grants Defendants' Motion for Judgment on the Pleadings, striking the willful infringement claims within Plaintiffs' Complaints. Plaintiffs cannot re-assert their claims with respect to willful infringement; however, this does not preclude future application to seek and recover attorneys fees if they can successfully argue that this case is "exceptional." See n.4, infra. Furthermore, Plaintiffs cannot presently make out an exceptional case allowing them to recover attorney's fees; discovery will be left to the discretion of the Honorable Tonianne Bongiovanni, U.S.M.J.

the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 ("FDCA"). The Act promulgated special provisions to the patent statutes aimed at streamlining the approval process for generic pharmaceuticals. 35 U.S.C. § 271(e)(2). A company seeking to market a new brand-name drug must submit a New Drug Application ("NDA"), which is generally a lengthy application that includes information about the drug such as evidence of its safety and effectiveness, and information about the patents that cover or might cover it. 35 U.S.C. § 355(b)(1). The Act permits a manufacturer seeking to market a generic equivalent of a previously approved Food and Drug Administration ("FDA") drug to file an Abbreviated New Drug Application ("ANDA") with the FDA to obtain approval for their generic drug, which essentially "piggyback[s] on the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs." See Celgene Corp. v. Teva Pharms. USA, Inc., 412 F. Supp. 2d 439, 441 (D.N.J. 2006) (internal citations omitted).

As part of the application process, an ANDA applicant must provide a certification as to each patent covering the previously-approved drug. 21 U.S.C. § 355(j)(2)(A)(vii). An applicant files a "paragraph IV certification," named after its statutory sub-paragraph, if the applicant believes "to the best of his knowledge . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug from which the application is submitted[.]" 21 U.S.C. § 355(j)(2)(A)(vii)(IV). An applicant that includes a paragraph IV certification must give notice to "each owner of the patent that is the subject of the certification . . . and . . . the holder of the approved [NDA]." 21 U.S.C. § 355(j)(2)(B)(iii). Upon receiving notice, a patent-holder has a forty-five-day period in which to bring an action for patent infringement before the FDA approves the ANDA. If a patent-holder does file a lawsuit, then the FDA will not approve the

ANDA until the court rules that the patent is not infringed or until thirty months have passed, beginning on the date the patent-holder received notice of the ANDA, whichever occurs first. See Id.

A patent infringement claim is generally made against "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor[.]" 35 U.S.C. § 271(a). The Act limits the potential patent liability to companies that seek FDA approval to market a generic version of the brand-name drug. See 35 U.S.C. §271(e)(1). Because a generic-drug manufacturer has not yet placed the drug into the market when it files an ANDA application, a patent-holder cannot make a claim for patent infringement under § 271(a). However, Section 271(e)(2)(A) "provides a jurisdictional basis for an infringement action against the applicant where it seeks approval to market a patented product before the expiration of the patent." Janssen, L.P. v. Barr Laboratories, Inc., 07-1515, 2008 U.S. Dist. LEXIS 7965, at *5 (D.N.J. Feb. 4, 2008); see also Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). Thereby, with this provision, Congress created a "highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." Janssen, 2008 U.S. Dist. LEXIS 7965 at *5 (quoting Eli Lilly, 496 U.S. at 678). Congress has extended the Court's jurisdiction over a hypothetical issue: whether the defendant's proposed generic drug would infringe on plaintiff's patent if the defendant's drug was on the market. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1366 (Fed. Cir. 2003).

B. Plaintiffs' Allegations

Since Defendants move for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) to strike the paragraphs in Plaintiffs' Complaints relating to willful infringement, the following version of events assumes Plaintiffs' allegations to be true.

Plaintiffs allege that Defendants infringed on five of their patents, specifically U.S. Patent Nos. 5,908,850 ("the '850 patent"), 6,355,656 (as reexamined) ("the '656 patent"), 6,528,530 ("the '530 patent"), 5,837, 482 ("the 1998 '284 patent"), and 6,635,284 ("the 2003 '284 patent") (collectively, "patents-in-suit"), listed in the FDA's Orange Book in conjunction with FOCALIN XR®, a product marketed by Novartis that is widely used in the treatment of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder. Pursuant to the Act, Defendants each filed ANDAs with the FDA seeking approval to market generic versions of Plaintiffs' FOCALIN XR extended release dexmethylphenidate hydrochloride capsules ("d-MPH extended release").[3] Defendants have also submitted paragraph IV certifications, attesting that Plaintiffs' patents-in-suit are invalid, unenforceable, and/or will not be infringed by Defendants' respective products. Defendants claim that they have not sold, offered to sell, or otherwise marketed d-MPH extended release products in the United States. Within the forty-five-day period provided by the Act, Plaintiffs filed the present Complaints for patent infringement against each of the Defendants. In its Complaints, Plaintiffs allege, among other things, that Defendants' infringement has been, and continues to be, willful and deliberate, which is the focus of the instant motions by Defendants.

[3]Teva filed ANDA No. 78-908 and notified Plaintiffs of the filings by letter dated August 3, 2007. Actavis filed ANDA No. 79-108 and notified Plaintiffs of the filings by letter dated September 26, 2007. IPC filed ANDA No. 78-992 and notified Plaintiffs of the filings by letter dated August 23, 2007. Barr filed ANDA No. 19-091 and notified Plaintiffs of the filings by letter dated October 5, 2007.

Defendants assert that Plaintiffs' only allegation of Defendants' infringement is based on Defendants' filing ANDAs, and under Federal Circuit and this District's own precedent, this artificial act of infringement is not willful infringement. Teva moves this Court to strike paragraphs 25, 30, 35, 40, and 45 of Plaintiffs' Complaint, in Civil Action No. 07-4459, relating to willful infringement. Actavis moves this Court to strike paragraphs 28, 33, 38, 43, and 48 of Plaintiffs' Complaint, in Civil Action No. 07-5367, relating to willful infringement. IPC moves this Court to strikedismiss paragraphs 26, 31, 36, 41, and 46 of Plaintiffs' Complaint, in Civil Action No. 07-4854, relating to willful infringement with prejudice. Barr moves this Court to dismiss paragraphs 29, 35, 41, 47, and 53 of Plaintiffs' Complaint, in Civil Action No. 07-5552, relating to willful infringement with prejudice. Defendants move this Court pursuant to Fed. R. Civ. P. 12(c) for judgment on the pleadings to strike these claims of willful infringement in Plaintiffs' Complaints because Plaintiffs cannot sustain, as a matter of law, these claims because they are based solely on the filing of an ANDA and a paragraph IV certification. Plaintiffs stipulate to withdraw the willfulness allegations, subject to renewing those allegations in the future if additional evidence is adduced; Plaintiffs argue that any request for relief beyond striking the willfulness allegations is premature, improper, and should be denied. The Court strikes the paragraphs in Plaintiffs' Complaints relating to willful infringement.

II. Discussion

A. Standard of Review

Defendants asks this Court to dismiss Plaintiffs' allegations of willful infringement contained in Plaintiffs' Complaints pursuant to Fed. R. Civ. P. 12(c). The standard that a court

applies on a motion for judgment on the pleadings pursuant to Rule 12(c) is the same standard that a court applies in deciding a motion to dismiss pursuant to Rule 12(b)(6). Turbe v. Government of Virgin Islands, 938 F.2d 427 (3d Cir. 1991); see also Spruill v. Gillis, 372 F.3d 218, 223 n. 2 (3d Cir. 2004). When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (internal citation and quotations omitted). In Bell Atlantic Corp. v. Twombly, 127 S.Ct. 1955 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Twombly, 127 S.Ct. at 1968 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 1965.

The Third Circuit has summed up the Supreme Court's Twombly formulation of the pleading standard as: "'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." Phillips, 515 F.3d at 234 (quoting Twombly, 127 S.Ct. at 1965). The Court will grant a motion under Rule 12(c) if "it appears beyond doubt that no relief could be granted under any set of facts which could be proved consistent with the allegations[.]" Celgene, 412 F. Supp. 2d 443. "Therefore, the narrow issue

before the Court is whether or not Defendant[s] could be found to have engaged in an act of willful infringement" in this case. Janssen, 2008 U.S. Dist. LEXIS 7965 at *9.

B. Willful Infringement

The Federal Circuit, in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1349 (Fed. Cir. 2004), found that an ANDA filing, without more, cannot support a judgment for willful infringement. See also Janssen, 2008 U.S. Dist. LEXIS 7965 at *12. The Federal Circuit has warned that a "trial court need not . . . elevate[] the ANDA certification into a finding of willful infringement." Yamanouchi Pharm. Co., LTD v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000). Thus, judges in this District, along with the many others inundated with similar motions by defendants in Hatch-Waxman Act cases where plaintiffs repeatedly allege willful infringement based only on the filing of an ANDA and relevant paragraph IV certifications, continue to emphasize to plaintiffs that they cannot go forward on such claims without more. See Janssen, 2008 U.S. Dist. LEXIS 7965 at *11-12 n. 1. Consistent with the overwhelming precedent and Plaintiffs' concession in this regard, the Court strikes the paragraphs previously articulated relating to Plaintiffs' allegations of willful infringement because of Defendants' mere filing of an ANDA and relevant paragraph IV certifications.

This holding does not prohibit Plaintiffs from seeking an "award [of] attorney's fees under section 285" if they later successfully argue that the instant case is "exceptional." 35 U.S.C. §§ 271(e)(4), 285. In Glaxo, the Federal Circuit stated that "exceptional cases" may arise where a court finds "inequitable conduct before the [United States Patent and Trademark Office], litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement." 376 F.3d at 1350. "The analysis required for a finding that a case is 'exceptional'

is distinct and separate from the issue of whether a plaintiff may allege a willful infringement claim in its complaint." Janssen, 2008 U.S. Dist. LEXIS 7965 at *13-14. However, "the mere fact that a company had filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." Glaxo Group Ltd, 376 F.3d at 1350-51. If Plaintiffs determine that circumstances exist, beyond Defendants' filing of the ANDA and paragraph IV certifications, that might justify a finding that this case is "exceptional" for purposes of seeking attorney's fees pursuant to 35 U.S.C. § 285, application may then be made, but such finding has no basis at this time. See Janssen, 2008 U.S. Dist. LEXIS 7965 at *14.[4] In addition, any discovery issues with regard to this issue of exceptional case discovery will be left to the magistrate judge's discretion.

III. Conclusion

For the foregoing reasons, the Court grants Defendants' Motions for Judgment on the Pleadings and the aforementioned paragraphs relating to willful infringement in the Complaints are stricken.

Dated November 5, 2008

/s/ Freda L. Wolfson
Honorable Freda L. Wolfson
United States District Judge

[4]As the Court holds that Plaintiffs cannot proceed with their willful infringement allegations based on Defendants' conduct to date, willful infringement cannot be among the exceptional circumstances for awarding attorney's fees unless and until actual infringement occurs. See Celgene Corp. v. Teva Pharms. USA, Inc., 412 F. Supp. 2d 439, 446 (D.N.J. 2006).